March 31, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

4197 '99 APR -6 A10:09

Reference: Docket N° 99D–0254
Draft Guidance for Industry on "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling"

Federal Register Notices: March 12, 1999 (Volume 64, Number 48) Pages 12341–12342

Dear Dr. Hubbard:

The undersigned, Jane Sinclair and Robert M. Sinclair, private citizens residing at 7202 Creeks Bend Drive, West Bloomfield, MI 48322, strongly support the FDA Draft Guidance for Industry entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling"

We were the owners of a prize toy poodle who was so adversely effected by Pfizer's veterinary drug Rimadyl (Carprofen) that she had to be euthanized June 8, 1998. In separate reports to the FDA dated October 30, 1998 and February 8, 1999 we indicated the following:

- We were misled by Pfizer's emotive Rimadyl broadcast commercials that continue to run on major television networks and many cable channels.
- We were not advised of potential side effects of Rimadyl (Carprofen) by the prescribing veterinarian.
- We did not receive a Rimadyl (Carprofen) Patient Information Leaflet.
- The prescribing veterinarian never showed us a Rimadyl (Carprofen) Product Label.
- Rimadyl merchandising materials provided to veterinary practitioners—calendars, toy "Rimadyl" dogs, desk pads—make no mention of potential side effects.
- Pfizer promotional messages to veterinarians say that Rimadyl is "safer than aspirin" and "good for your business".
- Extensive research pursued after our dog died reveals that...
  - thousands of U.S. dogs have suffered serious toxic effects including death,
  - Rimadyl (Carprofen) received by far the greatest number (33.3%) of "possibly drug-related ADE Animal Injury Reports" in 1997, and
  - the frequency and severity of toxic reactions to Rimadyl (Carprofen) in overseas markets where the drug has been approved are less than in the U.S. Pfizer' U.S. Rimadyl (Carprofen) Label Dosage is 110% of the Australia-U.K. Label Dosage for the first week and 220% thereafter.

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Our letters and reports are based on our experience with and research on Rimadyl (Carprofen), and include the recommendation that the FDA revise its "fair balance of risk and benefit information" policy and undertake rule-making toward a Federal Regulation requiring that:

- Consumer information prepared and supplied by the manufacturer must absolutely be delivered by veterinary providers to animal owners purchasing prescription drugs.
- Any veterinary practitioner or drug supplier failing to provide such information to animal owners can be held in violation of this Federal Regulation.
- The FDA will establish means to monitor compliance and will enforce this Regulation.

We also recommended that the FDA reinstitute its previous policy requiring that direct-to-consumer (DTC) advertising of prescription drugs in all media include a so-called "brief summary" of virtually all information, including hazards and contra-indications. FDA's August 8, 1997 easing of direct-to-consumer (DTC) broadcast advertising restrictions imposed on manufacturers of prescription drugs caused the Associated Press to report that "Advertisers expect the TV advertising blitz to increase" and Public Citizen's Dr. Sidney Wolf to say publicly that 'It's out of control" in January 1998. We object to DTC ads that mislead consumers by not providing a complete picture of the drug.

Purchasers and users of prescription drugs and biological products will benefit if the practices set forth in paragraphs II.A–II.E and paragraph III of the subject FDA Draft Guidance for Industry are followed.

The revision of the April 1994 Guidance that documents the applicability to animal prescription drugs and biological products is of particular importance to animal owners and their animals. It commands enthusiastic support.

The subject FDA Draft Guidance for Industry is a good step forward. Our recommendation is that additional FDA Rule Making address...

- the advertising and merchandising practices of prescription drug manufacturers/distributors and their sales representatives who call on medical and veterinary practitioners.
- the communication of fairly balanced risk and benefit information by medical and veterinary practitioners to purchasers and users of prescription drugs.

Sincerely,

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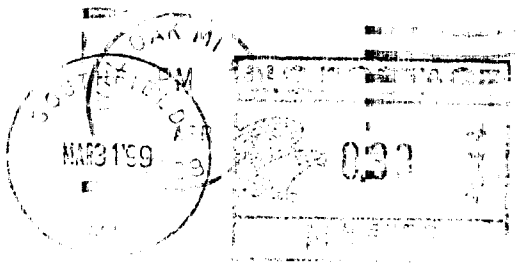

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